IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE YASMIN AND YAZ (DROPIRENONE) MARKETING, SALES PRACTICES AND RELEVANT PRODUCTS LIABILITY LITIGATION	: 3:09-md-02100-DRH-PMF MDL No. 2100 :
DEIDRE DAILEY,	: Judge David R. Herndon
Plaintiff,	: COMPLAINT AND JURY DEMAND :
vs.	
BAYER HEALTHCARE PHARMACEUTICALS, INC. BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, BAYER AG,	: Civil Action No.: 3:11-cv-13424-DRH-PMF : : : :
Defendants.	:

Plaintiff, DEIDRE DAILEY, by and through the undersigned counsel, on behalf of herself individually, upon information and belief, at all time hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

2. Plaintiff is filing this Complaint as permitted by Case Management Order No. 9 issued by Judge David R. Herndon of this Court. Plaintiff states that but for that Order permitting direct filing into the Southern District of Illinois, Plaintiff would have filed in the United States District Court for the Southern District of Ohio. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings this case be transferred to the Southern District of Ohio as set forth in Case Management Order No. 9.

3. This Court has personal jurisdiction over Defendants consistent with the United States Constitution and MDL No. 2100 as Plaintiff's claims arise out of Defendants' transaction of business and the commission of tortious acts within the State of Ohio, and by virtue of Defendants' substantial, continuous and systematic contacts with the State of Ohio and the State of Illinois unrelated to Plaintiff's claims.

PARTY PLAINTIFF

4. Plaintiff, DEIDRE DAILEY, is a citizen of the United States of America, and is a resident of Delaware County, Ohio.

5. Plaintiff, DEIDRE DAILEY, first began using Yaz, Yasmin, and/or Ocella in or about November 2007 and continued use until or about March 2008.

6. As a result of using Defendants' Yaz, Yasmin, and/or Ocella, Plaintiff DEIDRE DAILEY, was diagnosed with gallbladder disease in April 2008 and had a cholecystecomy on April 25, 2008, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

7. The injuries and damages sustained by Plaintiff, DEIDRE DAILEY, were caused by Defendants' Yaz, Yasmin, and/or Ocella.

8. Plaintiff did not know, nor could she have reasonably discovered through the use of reasonable diligence, that Yaz, Yasmin and/or Ocella wrongfully caused her injuries alleged herein and that she had a claim against Defendants until less than two years prior to the date of filing this action.

PARTY DEFENDANTS

9. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

10. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc. and BAYER HEALTHCARE PHARMACEUTICALS, INC. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

11. Upon information and belief, at all relevant times Defendants BAYER HEALTHCARE PHARMACEUTICALS, INC. has transacted and conducted business in the State of Illinois and in the State of Ohio, and derived substantial revenue from interstate commerce.

12. Upon information and belief, at all relevant time, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. expected or should have expected that its acts would have consequences within the United States of America, in the State of Ohio, and in the State of Illinois, and derived substantial revenue from interstate commerce.

13. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is the holder of approved New Drug Application No. 21-676 for YAZ.

14. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. markets YAZ, Yasmin, and Ocella in the United States.

15. Upon information and belief, Defendant, BAYER PHARMA AG is a pharmaceutical company domiciled in Germany.

16. Defendant BAYER PHARMA AG is formerly known as Schering AG and Bayer Schering Pharma AG and is the same corporate entity as Schering AG and Bayer Schering Pharma AG.

17. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006. Further, Bayer Schering Pharma AG was renamed Bayer Pharma AG effective July 1, 2011.

18. Upon information and belief, Defendant BAYER PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, Yasmin.

19. Upon information and belief, Defendant BAYER PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, YAZ.

20. Defendant BAYER PHARMA AG manufactures drospirenone and ethinyl estradiol, the progestin and estrogen contained in YAZ, Yasmin and Ocella.

21. Upon information and belief, Defendant BAYER PHARMA AG has transacted and conducted business in the State of Illinois and in the State of Ohio, and derived substantial revenue from interstate commerce.

22. Upon information and belief, Defendant BAYER PHARMA AG expected or should have expected that its acts would have consequences within the United States of America, in the State of Ohio, and in the State of Illinois, and derived substantial revenue from interstate commerce.

23. Upon information and belief, and at all relevant time Defendant BAYER PHARMA AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

24. Upon information and belief, Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

25. Upon information and belief, Defendant BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

26. At relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin.

27. At relevant times, Defendant BAYER CORPORATION conducted regular and sustained business in the State of Illinois and in the State of Ohio, by selling and distributing its products in the State of Illinois and engaged in substantial commerce and business activity in the State of Illinois and in the State of Ohio.

28. Upon information and belief, Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of Pennsylvania.

29. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC has transacted and conducted business in the State of Illinois and in the State of Ohio, and derived substantial revenue from interstate commerce. Defendant BAYER CORPORATION is the sole member of Defendant BAYER HEALTHCARE LLC and as such, for purposes of establishing diversity of citizenship, Defendant BAYER HEALTHCARE LLC is a citizen of Indiana and Pennsylvania.

30. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC expected or should have expected that its acts would have consequences within the United States of America, in the State of Illinois, and in the State of Ohio, and derived substantial revenue from interstate commerce.

31. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

32. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER SCHERING PHARMA AG.

33. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of Illinois and in the State of Ohio, and derived substantial revenue from interstate commerce.

34. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences

within the United States of America, in the State of Illinois, and in the State of Ohio, and derived substantial revenue from interstate commerce.

35. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG exercises dominion and control over Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER SCHERING PHARMA AG.

36. Upon information and belief, Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

37. Upon information and belief, Defendant BAYER AG is the third largest pharmaceutical company in the world.

38. Upon information and belief, and at all relevant times Defendant BAYER AG is the parent/holding company of all other named Defendants.

39. Upon information and belief, at all relevant times, Defendant BAYER AG has transacted and conducted business in the State of Illinois and in the State of Ohio, and derived substantial revenue from interstate commerce.

40. Upon information and belief, at all relevant times, Defendant BAYER AG expected or should have expected that its acts would have consequences within the United States of America, in the State of Ohio, and in the State of Illinois, and derived substantial revenue from interstate commerce.

41. Upon information and belief, at all relevant times, Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

42. Defendants, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER SCHERING PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG shall, hereinafter, be collectively referred to as "Bayer" or "Defendants."

NATURE OF THE CASE

Bayer's Combined Oral Contraceptives – Yasmin and Yaz

48. Yasmin and Yaz are birth control pills manufactured and marketed by Bayer. Ocella is the generic form of Yasmin. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

49. Yasmin and Yaz were approved by the Food and Drug Administration for marketing in 2001 and 2006 respectively.

Yasmin and Yaz Contain a "Fourth Generation" Progestin

50. The estrogen component in Yasmin and Yaz is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

51. Yasmin and Yaz are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.

52. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

53. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

54. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a Warning of the potentially increased risk of thrombosis.

55. Yasmin and Yaz contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

56. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and Yaz marketed under the trade name Ocella.

57. Since drospirenone is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA

approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

58. One possible mechanism of action is that drospirenone interacts differently with ethinyl estradiol compared to other progestins, such that it does not sufficiently counterbalance the clotting effects of estrogen as do other progestins, particularly the second generation progestins.

59. Another possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.

60. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

61. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

62. Indeed, during the brief time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

63. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

64. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

65. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and Yaz have been filed with the FDA.

66. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

67. Some deaths reported occurred in women as young as 17 years old.

68. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or Yaz.

Over-Promotion of Yasmin and Yaz

69. Defendants market Yasmin and Yaz as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

70. However, because Yasmin and Yaz contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

71. For example, prior to its integration with Defendant Bayer in 2006, Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

72. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"

73. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

74. More recently, Defendants advertised that its product Yaz was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the more serious condition of premenstrual dysphoric disorder or "PMDD."

75. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.

76. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone … which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

77. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

78. Indeed, the FDA felt Defendants' over promotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.

79. Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.

80. Barr Laboratories, Inc. And Teva Pharmaceuticals USA, Inc. Distribute, supply, sell, market, and/or introduce into interstate commerce, either directly or indirectly through third parties or related entities, the prescription oral contraceptive Ocella, which is the generic form of Yasmin.

81. According to Bayer's 2008 Annual Report, in April of 2005 Bayer filed suit against Barr Laboratories, Inc. alleging patent infringement by Barr for the intended generic version of Yasmin, In response, Barr Laboratories, Inc. filed a counter-claim against Bayer seeking to invalidate Bayer's patent for Yasmin, In March of 2008, the U.S. District Court for the District of New Jersey decided the matter and invalidated Bayer's patent for Yasmin.

82. Although Bayer appealed the federal court's ruling, in June of 2008 Bayer and Barr Laboratories entered into a supply and licensing agreement for a generic version of Yasmin covering the United States. Under the agreement, Bayer supplies Barr with a generic version of

Yasmin, which Barr markets solely in the United States under the name Ocella. In return, Barr pays Bayer a fixed percentage of its revenues from the Ocella sales.

83. Bayer ultimately lost its appeal on August 5, 2009, when the U.S. Court of Appeals for the Federal Circuit entered its opinion upholding the decision of the District of New Jersey and confirming the invalidity of Bayer's patent for Yasmin.

84. Bayer continues to manufacture the generic form of Yasmin for Barr, which is marketed and sold under the name Ocella.

85. The patient package insert and warnings label for Ocella bears the name Barr Laboratories, Inc.; however, it is essentially the same as the patient package insert and warnings label as Yasmin.

86. According to the publication Drug Topics, in 2008, while Yaz was ranked 28th and Yasmin ranked 56th, Ocella was ranked 96th among the top 200 branded drugs by total prescriptions.

87. Therefore, the Bayer defendants have benefitted and will continue to benefit economically in light of Ocella's large market share, and they bear liability for any harm caused by the product.

Plaintiff's Use of Yaz, Yasmin, and/or Ocella and Resulting Injuries

88. As a result of Defendants' claim regarding the effectiveness and safety of Yaz, Yasmin, and/or Ocella, Plaintiff DEIDRE DAILEY's medical provider prescribed and DEIDRE DAILEY began using Yaz, Yasmin, and/or Ocella in or about November 2007. Plaintiff DEIDRE DAILEY continued using Yaz, Yasmin, and/or Ocella until in or around March 2008. In or about April 2008, Plaintiff DEIDRE DAILEY was diagnosed with gallbladder disease and had a cholecystecomy on April 25, 2008.

89. As a direct and proximate result of using Yaz, Yasmin, and/or Ocella, Plaintiff DEIDRE DAILEY suffered the injuries described above.

90. Prior to Plaintiff's use of Yaz, Yasmin, and/or Ocella, Defendants knew or should have known that use of Yaz, Yasmin, and/or Ocella created a higher risk of gallbladder disease than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

91. Therefore, at the time Plaintiff used Yaz, Yasmin, and/or Ocella, Defendants knew or should have known that the use of Yaz, Yasmin, and/or Ocella created an increased risk to consumers of serious personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, stroke, gallbladder disease and even death.

92. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz, Yasmin, and/or Ocella, Defendants failed to adequately warn Plaintiff DEIDRE DAILEY and/or her health care providers of said serious risks before she used the products.

93. Had Plaintiff DEIDRE DAILEY and/or her heath care providers known of the increased risks and dangers associated with Yaz, Yasmin, and/or Ocella, she would not have used the product and would not have suffered from gallbladder disease and an ensuing cholecystecomy.

94. As a direct and proximate result of her use of Yaz, Yasmin, and/or Ocella, Plaintiff DEIDRE DAILEY has suffered significant harm, conscious pain and suffering, physical

injury and bodily impairment, including, but not limited to, suffering from gallbladder disease and an ensuing cholecystecomy, which has caused permanent effects, and which will continue in the future to cause her physical effects and damage which will affect her throughout her lifetime.

95. Further, as a direct and proximate result of her use of Yaz, Yasmin, and/or Ocella, Plaintiff DEIDRE DAILEY has suffered significant mental anguish and emotional distress and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

96. Plaintiff DEIDRE DAILEY has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of her use of Yaz, Yasmin, and/or Ocella.

FIRST CAUSE OF ACTION

Strict Products Liability Defective Manufacturing

97. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

98. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Yaz, Yasmin, and/or Ocella.

99. The Yaz, Yasmin, and/or Ocella oral contraceptives manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction such that it was unreasonably dangerous, was not fit for the ordinary purpose for which it was intended, and/or did not meet the reasonable expectations of an ordinary consumer.

100. The Yaz, Yasmin, and/or Ocella oral contraceptives manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction as described at the time it left the Defendants' control.

101. As a direct and proximate result of Plaintiff's use of Yaz, Yasmin, and/or Ocella as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff DEIDRE DAILEY suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

102. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Products Liability Defect in Design or Formulation

103. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

104. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz, Yasmin, and/or Ocella.

105. The Yaz, Yasmin, and/or Ocella oral contraceptives manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its design such that it was unreasonably dangerous, was not fit for the ordinary purpose for which it was intended, and/or did not meet the reasonable expectations of an ordinary consumer.

106. At the time Defendants manufactured, designed, distributed, sold, and/or supplied the Yaz, Yasmin, and/or Ocella oral contraceptives into the stream of commerce, a safer, more practical, alternative design was available.

107. The Yaz, Yasmin, and/or Ocella oral contraceptives manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants, was defective in design as described above at the time they left the Defendants' control.

108. As a direct and proximate result of Plaintiff's use of Yaz, Yasmin, and/or Ocella as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff DEIDRE DAILEY suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

109. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

Strict Products Liability Defect Due to Inadequate Warning

110. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

111. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz, Yasmin, and Ocella.

112. The Yaz, Yasmin, and/or Ocella oral contraceptives manufactured and supplied by Defendants was defective due to inadequate warning or instruction, because Defendants knew

or should have known that the product was unreasonably dangerous in that it created a substantial increased risk of serious bodily harm and death to reasonably foreseeable consumers such as Plaintiff DEIDRE DAILEY, and Defendants failed to adequately warn consumers and/or their health care providers of such increased risk.

113. The Yaz, Yasmin, and/or Ocella oral contraceptives manufactured and supplied by Defendants were also defective due to inadequate post-marketing warning or instruction, because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of Yaz, Yasmin, and/or Ocella, Defendants failed to provide adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

114. As a direct and proximate result of Plaintiff's use of Yaz, Yasmin, and/or Ocella as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff DEIDRE DAILEY suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

115. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

Strict Products Liability Defect Due to Nonconformance with Representations

116. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

117. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz, Yasmin, and/or Ocella, and they made representations regarding the character or quality of Yaz, Yasmin, and/or Ocella.

118. The Yaz, Yasmin, and/or Ocella oral contraceptives manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product.

119. Plaintiff DEIDRE DAILEY justifiably relied upon Defendants' representations regarding the Yaz, Yasmin, and/or Ocella oral contraceptives when she used Yaz, Yasmin, and/or Ocella.

120. As a direct and proximate result of Plaintiff's use of Yaz, Yasmin, and/or Ocella and her reliance on Defendants' representations regarding the character and quality of Yaz, Yasmin, and/or Ocella, Plaintiff DEIDRE DAILEY suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

121. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

Strict Products Liability Defect Due to Failure to Adequately Test

122. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

123. Defendants advised consumers and the medical community that Yaz, Yasmin, and/or Ocella contained the same safety profile as other oral hormonal birth control pills. However, Defendants failed to adequately test the safety of Yaz, Yasmin, and/or Ocella versus other oral hormonal birth control pills.

124. Had Defendants adequately tested the safety of Yaz, Yasmin, and/or Ocella versus other oral hormonal birth control pills and disclosed the results to the medical community or the public, Plaintiff would not have used, and her physician would not have prescribed, Yaz, Yasmin, and/or Ocella.

125. As a direct and proximate result of Defendants' failure to adequately test the safety of Yaz, Yasmin, and/or Ocella versus other oral hormonal birth control pills, Plaintiff DEIDRE DAILEY suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

126. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION

Negligence

127. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

128. Defendants had a duty to exercise reasonable care in the manufacture, design, sale, distribution, supply, marketing, and/or placement of Yaz, Yasmin, and/or Ocella into the stream of commerce, including a duty to ensure that its product did not pose a significantly increased risk of bodily harm and adverse events.

129. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yaz, Yasmin, and/or Ocella into interstate commerce in that Defendants knew, or should have known, that the product caused such significant bodily harm or death and was not safe for use by consumers.

130. Defendants also failed to exercise ordinary care in the labeling of Yaz, Yasmin, and/or Ocella and failed to issue to consumers and/or their health care providers adequate warnings of the increased risk of serious bodily injury or death due to the use of Yaz, Yasmin, and/or Ocella.

131. Despite the fact that Defendants knew or should have known that Yaz, Yasmin, and/or Ocella posed a serious increased risk of bodily harm to consumers, Defendants continued to manufacture and market Yaz, Yasmin, and/or Ocella for use by consumers.

132. Defendants knew or should have known that consumers, such as Plaintiff DEIDRE DAILEY, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

133. As a direct and proximate result of Defendants' negligence, Plaintiff DEIDRE DAILEY suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

134. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

SEVENTH CAUSE OF ACTION

Breach of Express Warranty

135. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

136. Defendants expressly warranted that Yaz, Yasmin, and/or Ocella was safe and effective prescription oral contraceptives.

137. The Yaz, Yasmin, and/or Ocella birth control products manufactured and sold by Defendants did not conform to these express representations because they caused serious injury to consumers who used the product when taken in the recommended dosages.

138. As a direct and proximate result of Defendants' breach of warranty, Plaintiff DEIDRE DAILEY suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

139. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

EIGHTH CAUSE OF ACTION

Breach of Implied Warranty

140. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

141. At the time Defendants manufactured, marketed, sold, and distributed Yaz, Yasmin, and/or Ocella, Defendants knew of the use for which Yaz, Yasmin, and/or Ocella was intended and impliedly warranted Yaz, Yasmin, and/or Ocella to be of merchantable quality, fitness, and safe for such use.

142. Plaintiff DEIDRE DAILEY and her health care provider reasonably relied upon the skill and judgment of Defendants as to whether Yaz, Yasmin, and/or Ocella was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.

143. Contrary to the implied warranty, Defendants' product Yaz, Yasmin, and/or Ocella was not of merchantable quality or safe for its intended use, because it was unreasonably dangerous as described herein.

144. As a direct and proximate result of Defendants' breach of warranty, Plaintiff DEIDRE DAILEY suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

145. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

NINTH CAUSE OF ACTION

Negligent Misrepresentation and/or Fraud

146. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

147. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yaz, Yasmin, and/or Ocella and, while engaged in the course of such business, made representations to Plaintiff and her physician regarding the character and/or quality of Yaz, Yasmin, and/or Ocella for guidance in their decision to select Yaz, Yasmin, and/or Ocella for Plaintiff's use.

148. Specifically, Defendants represented that their product was just as safe, and just as effective or more effective, than other birth control products on the market.

149. Defendants' representations regarding the character or quality of Yaz, Yasmin, and/or Ocella were untrue.

150. Defendants had actual knowledge based upon studies, published reports and clinical experience that their product Yaz, Yasmin, and/or Ocella created an unreasonable increased risk of serious bodily injury and death to consumers, or should have known such information.

151. Defendants negligently and/or intentionally misrepresented or omitted this information in their product labeling, promotions and advertisements and instead labeled, promoted and advertised their products as safe and effective in order to avoid losses and sustain profits in their sales to consumers.

152. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to its intended recipients, including Plaintiff and her physician.

153. Plaintiff DEIDRE DAILEY and her physician reasonably relied to her detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff DEIDRE DAILEY reasonably relied upon Defendants' representations to her and/or her health care providers that Yaz, Yasmin, and/or Ocella were just as safe and effective as other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the products.

154. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations, Plaintiff DEIDRE DAILEY suffered personal injury, economic and noneconomic damages, and will continue to suffer such harm, damages, and economic loss in the future.

155. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

TENTH CAUSE OF ACTION

Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act

156. Plaintiff DEIDRE DAILEY incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

157. At all times relevant, the Illinois Consumer Fraud & Deceptive Practices Act, 815 ILCS 505/1 et seq., (hereinafter "IFCA") prohibits "the use of any deception, fraud, false

pretense, false promise, misrepresentation or concealment, suppression or omission of any material fact…in the conduct of any trade or commerce" and declares such acts or practices as unlawful.

158. Defendants violated the IFCA by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Yaz, Yasmin and/or Ocella. Defendants communicated the purported benefits of Yaz, Yasmin and/or Ocella while failing to disclose the serious and dangerous side effects related to the use of Yaz, Yasmin and/or Ocella with the intent that consumers, like Plaintiff, and their healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Yaz, Yasmin and/or Ocella, respectively.

159. As a result of violating the ICFA, Defendants caused Plaintiff to be prescribed and to use Yaz, Yasmin and/or Ocella, causing severe injuries and damages as previously described herein.

ELEVENTH CAUSE OF ACTION

Violation of the Consumer Fraud Protection Statutes of Other States

160. Plaintiff DEIDRE DAILEY incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

161. Defendants engaged in commercial conduct by selling Yaz, Yasmin and/or Ocella.

162. Defendants misrepresented and omitted material information regarding Yaz, Yasmin and/or Ocella by failing to disclose known risks.

163. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation,

and/or the knowing concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the Yaz, Yasmin and/or Ocella, in violation of Ohio Rev. Code Ann. §§ 1345.01, *et seq.* and other similar statutes.

164. Ohio and all other states and the District of Columbia have enacted states to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that Yaz, Yasmin and/or Ocella were fit to be used for the purpose for which it was intended, when Defendants knew it was defective and dangerous, and by other acts alleged herein.

165. Defendants engaged in the deceptive acts and practices alleged herein in order to sell Yaz, Yasmin and/or Ocella to the public, including Plaintiff.

166. As a direct and proximate result of Defendants' violation of Ohio Rev. Code Ann. §§ 1345.01, *et seq.* and other various consumer protection statutes enacted in other states and the District of Columbia, Plaintiff has suffered damages, for which Plaintiff is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case

will be transferred for trial in accordance with Case Management Order #9 issued by United States District Court Judge David R. Herndon;

2. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care cost, medical monitoring, together with interest and cost as provided by law;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

4. Awarding all applicable statutory damages of the state whose laws will govern this action;

5. Awarding Plaintiff reasonable attorneys' fees;

6. Awarding Plaintiff the cost of these proceedings; and

7. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: December 1, 2011

RESPECTFULLY SUBMITTED,

/s/ Christopher L. Schnieders_____
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